# FIFRA Provisions on Reporting

#### INTRODUCTION

This memo reviews the provisions in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.A. 136 - 136y (FIFRA), for required reporting to EPA or the states by the regulated community, as well as the rulemaking authority to require reporting. FIFRA was first passed in 1947, extensively amended in 1972, and has subsequently been amended several more times, most recently by the Food Quality Protection Act of 1996.

FIFRA requires that before any person manufactures, sells, or distributes any pesticide in the U.S., they must first register the pesticide with EPA. Applications for registration must include the proposed label, directions for its use, a statement of all claims to be made for the pesticide, a confidential statement of the chemical formula, and data in support of the application. When reviewing the registration, EPA must classify each pesticide as either "general use" or "restricted use." "General use" pesticides may be applied by anyone, but "restricted use" pesticides may only be applied by certified applicators or persons working under the direct supervision of a certified applicator. Applicators are certified by a state if the state operates a certification program approved by EPA.

Pesticides registered prior to November 1, 1984 must undergo the reregistration process to bring original registration materials into compliance with the current requirements of FIFRA. Applicants may request an Experimental Use Permit to generate the information needed for a reregistration or original registration. All registrants must keep the Administrator updated on developments regarding unreasonable adverse effects of the registered pesticide and provide data for EPA's periodic review of all registrations. FIFRA also requires establishments that produce a regulated pesticide to register with EPA. FIFRA's generally applicable provisions include sections addressing recordkeeping and reporting, inspection of establishments, trade secret protection, applicator certification, and enforcement. Pesticide registration regulations can be found at 40 C F R 152-186

The main FIFRA programs that require or could require information to flow from the regulated community to EPA or the states cover the following areas:

- Registration and reregistration of pesticides;
- Experimental use permits;
- Registration of establishments;
- Certification of applicators;
- Application of restricted use pesticides; and
- Storage, disposal, transportation, and recall of pesticides.

Most of FIFRA's provisions pose no barrier to electronic reporting. In fact, several of them, such as the general rulemaking authority provisions, provide EPA with opportunities streamline reporting and information-provision requirements and amend ambiguous regulations. Some provisions are ambiguous about electronic reporting and will depend on how EPA regulations define certain terms and provide needed protections. They tend to relate to issues of trade secrets and confidential business information, provision of evidence, certification of data, rights to access and copy records, time-sensitive requirements, and copies. There are, however, a few provisions that pose a potential barrier to electronic reporting, generally involving one of the following requirements: written notification; written permission; certified mail; appropriate credentials; written statements; or enforcement.

## A. Registration of Pesticides

Section 136a prohibits the sale or distribution of any pesticide that is not registered by EPA. The section also establishes the pesticide registration procedures that applicants must follow, including filing a statement and supporting data with the Administrator.

Section 136a(a) authorizes EPA to prescribe regulations to the extent necessary to prevent unreasonable adverse effects on the environment. Regulations issued under this section could incorporate reporting requirements, that in turn, could provide for electronic reporting. Section 136a(a) does not pose a barrier to electronic reporting.

### Section 136a(a) Regulation of Unregistered Pesticides by Regulation

No barrier

[T]he Administrator may *by regulation* limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

Section 136a(c)(1) requires applicants for pesticide registration to file a statement with EPA. The statements must consist of several required components, including a copy of the labeling for the pesticide and, at the discretion of the Administrator, may include a full description of the tests conducted on the pesticide. The mandatory provision of a copy of the labeling is ambiguous about electronic reporting. EPA's regulations, however, specify that a required component of the application is "five legible copies of draft labeling (typescript or mock-up)." 40 C.F.R. 152.50(e). In addition, 40 C.F.R. 156.10(a)(6) requires registrants to submit "final printed labeling," a requirement that can be satisfied by reproductions, or reproduction quality microfilm, or photo reductions for unusual labels.

Section 136a(c)(1) Filing of Statement Ambiguous	Section 136a(c)(1) Filing of Statement	Ambiguous
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Each applicant for registration of a pesticide *shall file* with the Administrator a statement which includes (...) (C) a complete *copy* of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use; (...).

As set out in section 136a(c)(1), a copy of the pesticide label is a required component of a complete application. Labeling can subsequently be modified if the registrant notifies EPA in writing 60 days prior to distribution or sale of the labeled product, as authorized by section 136a(c)(9) (C)(i)(A). The Administrator may then approve or deny the modification. The requirement that this notice must be in writing poses a potential barrier to electronic reporting.

## Section 136a(c)(9) (C)(i)(A) Labeling Modifications

Potential barrier

A registration *may* be modified if the registrant notifies the Administrator *in writing* (...).

As part of the application procedure, applicants must submit data is support of their registration. There are restrictions on what data will suffice that may impact the feasibility of electronic reporting. For example, under section 136a(c)(1)(F)(i), data submitted to support the original application of a pesticide registered after September 30, 1978, or to amend an original registration to add a new use, is only sufficient if the applicant secures the written permission of original data submitters. Written permission is a requirement for ten years after the original registration date.

## Section 136a(c)(1)(F)(i) Data in Support of Application

Potential barrier

(...) data submitted (...) shall not, *without the written permission* of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide (...).

Section 136a(c)(1)(F)(iii) similarly addresses data whose original submitter is not the present applicant. It states that for an application within 15 years of the original registration, the Administrator has discretion to consider such data without the written consent of the original submitter if the applicant submits an offer to compensate the original data submitter and presents the Administrator with evidence of the delivery of the offer. Depending on how the requirements for "evidence" and for an "offer" are interpreted by the EPA, this provision could impact electronic reporting, and the requirement for written consent poses a potential barrier as discussed above.

**Ambiguous** 

Except as otherwise provided in clause (i), (...) the Administrator *may*, without the permission of the original data submitter, consider any such item of data in support of an application (...) within the fifteen-year period following the date the data were originally submitted only if the applicant has made an *offer to compensate* the original data submitter and submitted such offer to the Administrator *accompanied by evidence of delivery to the original data submitter of the offer*. (...)

Finally, section 136a(c)(1)(vi) could pose a similar barrier to electronic reporting due to its requirement that data be accompanied by written permission from the original data submitter.

#### Section 136a(c)(1)(vi) Data submitted – Additional Requirements

Potential barrier

With respect to data submitted after August 3, 1996, (...), if such data relates solely to a minor use of a pesticide, such data shall not, *without the written permission* of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. (...)

In order to clarify what information may be required from applicants, section 136a(c)(2)(A) directs the Administrator to publish guidelines and revise them periodically. The guidelines do not pose any barrier to electronic reporting and may actually help to authorize EPA in requiring electronic reporting.

## Section 136a(c)(2)(A) Guidelines on Data in Support of Registration

No barrier

The Administrator *shall publish guidelines* specifying *the kinds of information which will be required* to support the registration of a pesticide and *shall revise such guidelines* from time to time.

The Administrator retains the discretion to request additional data from an applicant. Section 136a(c)(2)(B)(ii) provides that the registrant must satisfy any such request by providing evidence demonstrating that it is taking appropriate steps to obtain the information. Whether or not this provision poses a barrier to electronic reporting will depend on how EPA defines "evidence."

#### Section 136a(c)(2)(B)(ii) Evidence of Compliance with Data Requirements

**Ambiguous** 

Each registrant of such pesticide *shall provide evidence* (...) that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent (...).

EPA is directed by section 136a(c)(2)(B)(viii)(I) to coordinate data requirements of federal and state authorities and develop a process to streamline this effort in the future. It is possible that electronic reporting could be authorized because it is a method of streamlining the application process and eliminating redundancy.

#### Section 136a(c)(2)(B)(viii)(I) Coordination of Federal and State Data Requirements

No barrier

If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant. (II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I). (III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

Section 136a(c)(2)(C) authorizes the Administrator to prescribe simplified procedures for registration. Regulations prescribed pursuant to this authority could include electronic reporting requirements.

## Section 136a(c)(2)(C) Regulations to Simplify Procedures

No barrier

Within nine months after September 30, 1978, the Administrator shall, *by regulation*, prescribe simplified procedures for the registration of pesticides (...).

Section 136a(c)(7) governs instances where EPA conditionally registers a pesticide or amends the registration of a pesticide. Applicants are required by this section to satisfy registration requirements similar to general applicants. Therefore, the same analysis as applied to the provisions for statement filing and data submission apply to conditional registrations as well (see section 136a(c)(1) above).

#### Section 136a(c)(7) Registration Under Special Circumstances

No barrier

(...) An applicant seeking conditional registration or amended registration under this subparagraph *shall submit such data as would be required* to obtain registration of a similar pesticide under paragraph (5).

In addition to issuing guidelines for data submission, EPA is directed by section 136a(c)(10) to develop procedures and guidelines to expedite the review of pesticide registration applications. It is possible that these procedures and guidelines could include electronic reporting because it would help to simplify review procedures.

#### Section 136a(c)(10) Procedures and Guidelines to Expedite Review

No barrier

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, *develop procedures and guidelines, and expedite the review of an application for registration* of a pesticide or an amendment to a registration that satisfies such guidelines.

As part of the registration process, section 136a(d) requires the Administrator to classify a pesticide as being for general or restricted use. Pursuant to section 136a(d)(1)(C)(ii), the Administrator is authorized to promulgate regulations restricting the use of a pesticide that may cause unreasonable adverse effects on the environment. This rulemaking authority could also be used to adopt electronic reporting.

#### Section 136a(d)(1)(C) (ii) Pesticides Subject to Use Restrictions

No barrier

If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator *may provide by regulation*. (...)

Pursuant to section 136a(d)(3), the registrant of any restricted use pesticide may petition the Administrator to change its classification from restricted to general use. The petition is required to explain why restricted use classification is unnecessary and demonstrate why general use would not cause unreasonable adverse effects on the environment. Such petitions could be submitted electronically under the general language of this section.

### Section 136a(d)(3)Change in Classification

No barrier

The registrant (...) may *petition* the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment.

Section 136a(g) provides for periodic review of registrations pursuant to regulations prescribed by the Administrator. The Administrator is authorized to request data from registrants to assist in the review process, and could issue regulations authorizing electronic methods for submitting those data.

## Section 136a(g) Periodic Review of Registrations

No barrier

(1)(A) The registrations of pesticides are to be periodically reviewed. The Administrator *shall by regulation* establish a procedure for accomplishing the periodic review of registrations (...).

(2)(A) Data submission required. The Administrator shall use the authority in subsection (c)(2)(B) of this section to require the *submission of data* when such data are necessary for a registration review.

Section 136a(h) sets out the registration requirements for antimicrobial pesticides. Subsection 136a(h)(3)(a)(i) requires the Administrator to issue regulations to accelerate and improve the review of antimicrobial pesticide products. Subsection 136a(h)(3)(a)(iii) directs the

Administrator to consider several options in drafting its regulations, including the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, the establishment of a certification process by approved laboratories as an adjunct to the review process, appropriate and cost-effective review mechanisms such as the expanded use of notification and non-notification procedures, and revised procedures for application review. EPA regulations could provide for electronic certification, assuming that such certifications can be properly authenticated.

## Section 136a(h)(3)(A)(i) Expedited Review of Antimicrobial Pesticide Registrations

No barrier

The Administrator *shall issue final regulations* not later than 240 days after the close of the comment period for the proposed regulations. (...)

## B. Reregistration of Pesticides

The general rule set out in section 136a-1(a) directs the Administrator to reregister each pesticide first registered before November 1, 1984. An exception is provided for pesticides that the Administrator has determined (after November 1, 1984 and before the effective date of this section) to have no outstanding data requirements.

Section 136a-1 (b) outlines the five phases of the reregistration process which are: (1) listing of the active ingredients of the pesticides that will be reregistered; (2) submission to the Administrator of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period; (3) submission to the Administrator by registrants of certain certificated information; (4) independent, initial review by the Administrator of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data; and (5) review by the Administrator of data submitted for reregistration and appropriate regulatory action by the Administrator.

Under Section 136a-1(d)(1), the registrant must notify EPA by certified mail that it intends to reregister its pesticide and submit the required information within the statutorily prescribed time. The certified mail requirement poses a potential barrier to electronic reporting.

## Section 136a-1(d) Re-registration Notification

Potential barrier

(2) The registrant of a pesticide containing an active ingredient listed under (...) this section *shall notify* the Administrator by *certified mail* whether the registrant intends to seek or does not intend to seek reregistration of the pesticide (...).

Section 136a-1(d)(3) defines the procedure for fulfilling outstanding data requirements for reregistration. In sum, this section requires the submission of outstanding data or a commitment to replace data that was submitted, yet is inadequate. Therefore, the data submission requirements as applied in section 136a(c) apply and pose the same potential barriers to electronic reporting, such as writing requirements (see above). In addition, how "commitment" is interpreted will affect EPA's ability to authorize electronic reporting.

## Section 136a-1(d)(3) Missing or Inadequate Data

No barrier

Each registrant of a pesticide that contains an active ingredient listed under (...) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide **shall submit** to the Administrator - (A) (...) (i) **all data that are required by regulation** to support the registration of the pesticide with respect to such active ingredient; (ii) **data that were submitted** by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and (iii) **data identified** under clause (i) that have not been submitted to the Administrator; and (B) either - (i) a **commitment** to replace the data identified under subparagraph (A)(ii) [inadequate data that was submitted] and submit the data identified under subparagraph (A)(iii) [data not yet submitted] (...).

Section 136a-1(d)(3) provides that data must be deemed inadequate if the source of the data is a study for which the registrant is unable to certify that the registrant has access to the raw data used in or generated by such study, as prescribed by section 136a-1(e)(1)(G), although that section does not clarify what qualifies as certification (see discussion below). This certification requirement is a potential barrier to electronic reporting, which depends in part on how EPA has defined certification in its regulations.

#### Section 136a-1(d)(3) Certification of Raw Data

Potential barrier

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the *certification* prescribed by subsection (e)(1)(G) of this section that the registrant possesses or has access to the raw data used in or generated by such study.

Section 136a-1(e) describes phase three of the reregistration process in more detail. Phase three is the submission by registrants of certain certified information to the Administrator. Each registrant of a pesticide, which contains one or more specified active ingredients, who has submitted a notice of an intent to seek the reregistration must submit summaries of studies conducted on the pesticide's active ingredient(s) and a certification that the registrant or the Administrator has access to the raw data used in or generated by the summarized studies. As stated above, the certification requirement poses a potential barrier to electronic reporting. The registrant must also submit either a commitment to submit data to fill each outstanding data requirement or an offer to share in the cost of developing such data to be incurred by a person

who has made a commitment to submit such data.

#### Section 136a-1(e)(1) Submission of Required Information

Potential barrier

Each registrant of a pesticide that contains an active ingredient (...) shall submit (...) to the Administrator - (A) a summary of each study (...) (G) a *certification* (...) used in or generated by the studies (...); (H) either - (i) a *commitment to submit data* to fill each outstanding data requirement identified by the registrant; or (ii) an *offer to share in the cost of developing such data* to be incurred by a person who has made a commitment (...) to submit such data, (...).

Section 136a-1(e)(1) also provides penalties for registrants who submit false certifications under subsection (G). The impact of this provision on an electronic reporting requirement is ambiguous and depends on how certifications are defined in EPA's regulations.

#### Section 136a-1(e)(1) Penalties for False Certification

Potential barrier

A registrant who *submits a certification* under subparagraph (G) that is false shall be considered to have violated this subchapter and shall be subject to the penalties prescribed by section 136l of this title.

The summaries described in 136a-1(e)(1) may not always be sufficient. Pursuant to section 136a-1(f), the Administrator can request the complete study. The provision of copies of the studies is ambiguous about electronic reporting, but EPA regulations could interpret copies to include electronic versions.

## Section 136a-1(f)(1) Independent review and Identification of Outstanding Data Requirements

**Ambiguous** 

(A) To assist the review of the Administrator under this subparagraph, the Administrator *may require* a registrant seeking reregistration *to submit complete copies* of studies summarized under subsection (e)(1) of this section.

Pursuant to section 136a-1(e)(4), the Administrator must issues guidelines for supplying this required data, which could incorporate an electronic reporting option.

### Section 136a-1(e)(4) Guidelines for Studies to be Submitted

No barrier

(A) (...) the Administrator, by order, *shall issue guidelines* to be followed by registrants in - (i) summarizing studies; (ii) reformatting studies; (iii) identifying adverse information; and (iv) identifying studies that have been submitted previously that may not meet the requirements of section 136a of this title or regulations issued under such section, under paragraph (1).

Section 136a-1(i)(7) concerns the apportionment of fees for pesticide active ingredients used in food or feed products. It authorizes EPA to request reports from registrants for the purpose of determining their respective market shares, which will form the basis for the fee. Nothing in this provision poses a barrier to electronic reporting, and an EPA order could be used to allow electronic methods for those reports.

#### Section 136a-1(i)(7) Fee Apportionment Among Registrants

No barrier

(A) If two or more registrants are required to pay any fee prescribed by paragraph (1), (2), or (3) with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales (...) (B) The Administrator, by order, may require any registrant to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion fees (...).

## C. Experimental Use Permits

Under section 136c(a), any person may apply for an experimental use permit (EUP) for a pesticide in order to generate information needed to register the pesticide. The EUP is subject to the terms and conditions that the Administrator prescribes in the permit, and EPA could include electronic reporting for EUP's as a permit condition.

## Section 136c(c) Experimental Use Permits

No barrier

Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such *terms and conditions* and be for such period of time as the Administrator may prescribe *in the permit*.

Pursuant to section 136c(d), the Administrator may require the permittee to conduct studies and report the results. This provision does not present a barrier to electronic reporting, and the Administrator could by regulation authorize such studies to be electronically submitted.

#### Section 136c(d) Conditions in Permits

No barrier

When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator *may specify that studies be conducted* to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. *All results of such studies shall be reported* to the Administrator before such pesticide may be registered under section 136a of this title.

Under section 136c(f), the Administrator may prescribe regulations authorizing the states to

issue EUPs. These regulations could allow states to incorporate electronic reporting for EUP's.

Section 136c(f) State Issuance of EUPs	No barrier
Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as the Administrator <i>may by regulations prescribe</i> ,	
authorize any State to issue an experimental use permit for a pesticide ().	

### D. Administrative Review and Suspension of Registrations

After a pesticide has been registered, registrants are required by section 136d(a)(2) to keep the Administrator updated as to any additional information that arises concerning unreasonable adverse effects of the pesticide. While there is no barrier to electronic reporting in the statutory language, the regulations present a potential barrier. 40 C.F.R. section 159.156 requires the additional information to be sent to EPA by certified or registered mail, delivered in person or by courier service, or delivered by other methods as EPA deems appropriate. It is possible that electronic reporting of this information could be deemed appropriate in future amendments to the regulations, but the provision is ambiguous as it stands.

Section	136d(a)	(2) Infe	ormation o	n Uni	easonable A	dverse Eff	ects	Aml	biguous
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If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant *shall submit* such information to the Administrator.

Transfers of registration for minor agricultural use are permitted pursuant to section 136d(f)(3). An application for such a transfer must comply with regulations adopted by the Administrator. This provision does not present a barrier to electronic reporting and may offer an opportunity for EPA to adopt electronic methods of applying for a transfer.

Section 136d(f)(3) Transfers of Registration	No barrier	
()(B) An application for transfer of registration, in conformance with <i>any regul Administrator may adopt</i> with respect to the transfer of the pesticide registration to the Administrator ().		

Section 136d(g)(1) requires registrants, pesticide producers, pesticide exporters, and other specified individuals who possess any canceled or suspended pesticide to notify EPA about the pesticides in their possession. This reporting provision poses no barrier to electronic reporting, because that notice can be provided by any method, including electronic reporting. But the Administrator is then required to transmit a copy of the notice to the regional office of EPA with jurisdiction over the place of pesticide storage. This provision for a copy of the notice to be sent to the regional office has an ambiguous impact on electronic reporting since it is not clear that an

electronic notice will be authorized nor whether an electronic copy of the notice would suffice. On the other hand, if EPA authorizes registrants and others to provide such notice electronically, it then would be relatively easy to transmit an electronic copy to the appropriate regional office.

## Section 136d(g)(1) Notice of Stored Pesticides with Canceled or Suspended Registrations.

Ambiguous

- (1) Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section *shall notify* the Administrator and appropriate State and local officials of (A) such possession, (B) the quantity of such pesticide such person possesses, and (C) the place at which such pesticide is stored.
- (2) The Administrator shall *transmit a copy of each notice* submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

## E. Registration of Establishments Producing Pesticides

Under section 136e(a), any establishment which produces a pesticide subject to FIFRA must be registered with the Administrator. Applying for registration of an establishment is not a complicated process. The application must include the name and address of the establishment and of the producer who operates the establishment. When EPA receives an application containing this information, it must register the establishment and assign it an establishment number. No barrier to electronic reporting is evident from the statutory language, and such registrations could be handled electronically.

#### Section 136e Registration of Establishments

No barrier

- (a) The application for registration of any establishment *shall include* the name and address of the establishment and of the producer who operates such establishment.
- (b) Whenever the Administrator receives an application under subsection (a) of this section, the Administrator shall register the establishment and assign it an establishment number.

Once registered, section 136e(c)(1) requires the producer to inform the Administrator of the types and amounts of pesticides and active ingredients that it will use in the production of pesticides. The producer must submit annual updates of this information under such regulations as the Administrator may prescribe. The regulations specify that reports must be submitted on "forms supplied by the Agency." 40 C.F.R. 167.85(c). Thus, EPA's regulations could allow for electronic forms that could be supplied on EPA's website.

#### Section 136e(c) Information Required of Registered Establishments

No barrier

(1) Any producer operating an establishment registered under his section *shall inform* the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides (...) The information required by this paragraph shall be kept current and *submitted to the Administrator annually as required under such regulations as the Administrator may prescribe*.

Section 136e(c) also requires pesticide producers to inform the EPA of the name and address of anyone to whom the producer has provided any pesticide. This provision does not pose any barrier to electronic reporting.

#### Section 136e(c) Reporting of Name and Address of Pesticide Recipients

No barrier

(2) Any such producer *shall*, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 136k of this title, *inform* the Administrator of the *name and address of any recipient of any pesticide* produced in any registered establishment which the producer operates.

## F. General Recordkeeping and Reporting Requirements

Section 136f requires producers, registrants, and applicants to maintain records that the Administrator deems necessary for environmental pesticide control. It also covers the right of the Administrator to inspect and copy these records, and authorizes EPA to adopt regulations for recordkeeping and reporting. The provision has an ambiguous impact on electronic reporting since it does not explain how records could be made available for inspection and copying electronically if paper records are no longer kept, but it may also provide an opportunity for EPA to authorize these activities through electronic means.

## Section 136f(a) Books and Records Requirements

Ambiguous

(a) Requirements. The Administrator *may prescribe regulations requiring* producers, registrants, and applicants for registration *to maintain* such records with respect to their operations and the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this subchapter and *to make the records available for inspection and copying* in the same manner as provided in subsection (b) of this section (...).

Section 136f(b) requires any producer, distributor, carrier, dealer, or other person who sells or delivers pesticides subject to FIFRA's provisions to provide records to EPA or duly designated state or to permit access to and copying of such records. It is unclear how this requirement would apply if a producer or distributor uses electronic reporting and no longer keeps paper copies of its records and whether the right to access and copy records could include electronic data.

#### Section 136f(b) Right to Access and/or Copy Records

Ambiguous

For the purposes of enforcing the provisions of this subchapter, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this subchapter, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, *furnish or permit such person at all reasonable times to have access to, and to copy*: (1) *all records* showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee (...).

Section 136f(b) limits the scope of EPA or state records inspection. It specifies that inspections will not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data not related to registered pesticides. In addition, the section provides that before undertaking an inspection, the officer or employee must present appropriate credentials and a written statement as to the reason for the inspection. The required access to copy and presentation of credentials have an ambiguous effect on electronic reporting, and the written statement poses a potential barrier to electronic reporting.

#### Section 136f(b) Inspection of Records

Ambiguous/ Potential barrier

(...) any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this subchapter, shall (...) *furnish or permit* such person at all reasonable times to have *access* to, and to *copy*: (1) all records showing the delivery, movement, or holding of such pesticide or device (...) Any inspection with respect to any records and information referred to in this inspection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (...) the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, *appropriate credentials* and a *written statement* as to the reason for the inspection (...).

## G. Inspection of Establishments

Section 136g allows the EPA or state inspectors to enter property where pesticides or devices are held for distribution or sale in order to inspect and take samples of pesticides, containers, labels, and devices for the purposes of enforcing the provisions for controlling environmental pesticides. The provision's right to enter, inspect, and sample establishments and other places has an ambiguous impact on electronic reporting because it is unclear whether electronic data are included. The requirements of appropriate credentials and a written statement pose potential barriers to electronic reporting because it is unclear if they can be satisfied by electronic means.

Section 136g(a)(1) Right of Entry, Inspection, and Sampling	Ambiguous/ Potential barrier
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(...) officers or employees of the Environmental Protection Agency or of any State duly designated by the Administrator are authorized to enter at reasonable times (A) any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices, or (B) any place where there is being held any pesticide the registration of which has been suspended or canceled (...).

(2) Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, *appropriate credentials* and a *written statement* as to the reason for the inspection, (...).

Section 136g(b) explains that EPA officers or duly designated employees are empowered to obtain and execute warrants in order to enforce the statutes provisions. The warrants may authorize entry and inspection of establishments, copying of records, and seizure of pesticides or devices in violation of FIFRA. This section has an ambiguous impact on electronic reporting as it is not clear if electronic data are covered by its entry, inspection, and copying requirements.

#### Section 136g(b) Warrants

Ambiguous

(1) entry, inspection, and copying of records for purposes of this section or section 136f of this title; (2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this subchapter and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and (3) the seizure of any pesticide or device which is in violation of this subchapter.

Section 136g(c) specifies that the examination of pesticides or devices for compliance with FIFRA must be conducted in the EPA or in another designated location. If the Administrator concludes from the examination that a violation has occurred, it shall notify the person against whom proceedings are contemplated and certify the facts to the Attorney General. The provision poses a potential barrier to electronic reporting both in that it permits anyone charged with a FIFRA violation to present their views orally or in writing and in that it directs the Administrator to certify facts to the Attorney General with a copy of the results of its analysis of the pesticide in question.

### Section 136g(c) Enforcement

Ambiguous

(1) If it shall appear from any such examination that they *fail to comply* with the requirements of this subchapter, the Administrator shall cause *notice to be given to the person* against whom criminal or civil proceedings are contemplated. Any person so notified shall be given an *opportunity to present the person's views, either orally or in writing*, with regard to such contemplated proceedings, and if in the opinion of the Administrator it appears that the provisions of this subchapter have been violated by such person, then the Administrator shall *certify the facts* to the Attorney General, *with a copy of the results of the analysis* or the examination of such pesticide for the institution of a criminal proceeding pursuant to section 136l(b) of this title or a civil proceeding under section 136l(a) of this title, when the Administrator determines that such action will be sufficient to effectuate the purposes of this subchapter.

## H. Protection of Trade Secrets and Other Confidential Information

Section 136h protects trade secrets and other sensitive information by permitting it to be marked and submitted separately. In general, the Administrator can not make public information which contains or relates to trade secrets or other confidential or privileged information. This section mandates that certain information concerning tests on registered pesticides and their effects on organisms and the environment shall be available for disclosure to the public. It does not, however, authorize the disclosure of information that would reveal trade secrets. This provision poses a potential barrier to electronic reporting. For an electronic reporting option to be authorized under this provision of FIFRA, it must both ensure that information is available to the public and provide safeguards to protect the confidentiality of information qualifying as a trade secret or otherwise protected information under this section.

#### Section 136h Trade Secrets and Other Information Disclosure

Potential barrier

- (a) (...) the applicant may (1) clearly mark any portions thereof which in the applicant's opinion are *trade secrets or commercial or financial information* and (2) submit such marked material separately from other material required to be submitted under this subchapter.
- (b) (...) the Administrator shall not make public information which (...) relates to *trade secrets or commercial or financial information* obtained from a person and privileged or confidential (...).
- (d) (1) All information concerning the objectives, methodology, results, or significance of any test (...) and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment (...) *shall be available for disclosure to the public.* (...) This paragraph does not authorize the disclosure of any information that discloses (...) unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

## I. Applicators and Use of Restricted Use Pesticides

Section 136i concerns the procedure for certifying applicators of pesticides. States can submit certification plans to the Administrator for approval. For those states whose plans have not been approved, the Administrator is authorized to conduct a certification program. In these states, the Administrator may by regulation require any person engaging in the commercial application, sale, or distribution of any pesticide, which has been classified for restricted use, to maintain records and submit reports concerning the commercial application, sale, or distribution of the pesticide. The Administrator must prescribe standards for the certification of applicators of pesticides and may require any pesticide dealer participating in a certification program to be licensed under a state licensing program approved by the Administrator. EPA regulations could authorize electronic reporting of records and reports and electronic certification of applicators.

#### Section 136i(a) Applicator Certification Procedure

Ambiguous

- (1) Federal certification. In any State for which a State plan for applicator certification has not been approved (...) the Administrator (...) may require any person (...) to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. (...) The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by the Administrator.
- (2) State certification. If any State (...) desires (...) the Governor of such State shall submit a State plan for such purpose. (...)

## J. Recordkeeping for Restricted Use Pesticides

Section 136i-1(a) directs the Secretary of Agriculture, in consultation with the Administrator of EPA, to require certified applicators of restricted use pesticides to maintain records comparable to records maintained by commercial applicators of pesticides in each state. The records must comply with state requirements for the maintenance of records. If no such requirements exist, the applicator shall maintain records that contain the following information: product name, amount, approximate date of application, and location of application of each such pesticide used for a two-year period after such use. This requirement has an ambiguous impact on electronic reporting since it is unclear if electronic, rather than paper, records can be maintained. This section also requires certified applicators to provide a copy of the records they maintain to the person for whom such application was provided. Whether or not this provision poses a barrier to electronic reporting depends on whether EPA regulations authorize electronic copies.

#### Section 136i-1(a) Pesticides Recordkeeping

Ambiguous

(1) The Secretary of Agriculture (...) shall require certified applicators of restricted use pesticides (...) to *maintain records* comparable to records maintained by commercial applicators of pesticides in each State. If there is no State requirement for the maintenance of records, such applicator *shall maintain records* that contain the product name, amount, approximate date of application, and location of application of each such pesticide used for a 2-year period after such use.

(2) Within 30 days of a pesticide application, a commercial certified applicator shall provide a *copy* of records maintained under paragraph (1) to the person for whom such application was provided.

Under section 136i-1(b), records maintained under section 136i-1(a) must be made available upon request to any federal or state agency that deals with pesticide use or any health or environmental issue related to the use of pesticides. This provision does not pose a barrier to electronic reporting as long as the technology includes adequate safeguards to avoid disclosing individual identities of producers.

## Section 136i-1(b) Access to Pesticides Records

No barrier

Records (...) *shall be made available* to any Federal or State agency that deals with pesticide use or any health or environmental issue related to the use of pesticides (...). Each such Federal agency shall conduct surveys and record the data from individual applicators to facilitate statistical analysis for environmental and agronomic purposes, *but in no case may a government agency release data* (...) that would directly or indirectly reveal the identity of individual producers.

Section 136i-1(c) allows health care personnel to request and receive information about a pesticide when necessary to provide medical care. This provision is ambiguous about electronic reporting because it requires prompt provision of the record and label of a pesticide to the health care professional, and those items may not be available in electronic format.

## Section 136i-1(c) Health Care Personnel Access to Information

**Ambiguous** 

When a health professional determines that pesticide information maintained under this section is necessary to provide medical treatment or first aid to an individual who may have been exposed to pesticides for which the information is maintained, upon request persons required to maintain records under subsection (a) of this section *shall promptly provide record and available label information* to that health professional. In the case of an emergency, such record information shall be provided immediately.

Section 136i-1(f) directs the Secretary of Agriculture and EPA Administrator to maintain a database reflecting information contained in records maintained under section 136i-1(a) and to publish an annual report. The provision does not pose a barrier to the maintenance of an electronic database and could be used by EPA as authority for requiring electronic recordkeeping

and reporting for restricted use pesticides and to publish the annual report electronically.

## Section 136i-1(f) Surveys and Reports

No barrier

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency, shall survey the records maintained under subsection (a) of this section to develop and *maintain a data base* that is sufficient to enable the Secretary and the Administrator to *publish annual comprehensive reports* concerning agricultural and nonagricultural pesticide use (...).

Under section 136i-1(g), the Secretary of Agriculture and the Administrator of EPA shall promulgate regulations implementing this section on recordkeeping for restricted use pesticides. No barrier to electronic reporting is presented by this provision, and it may be used by EPA to authorize electronic reporting in its regulations.

## Section 136i-1(g) Pesticides Recordkeeping Regulations

No barrier

The Secretary of Agriculture and the Administrator of the Environmental Protection Agency *shall promulgate regulations* on their respective areas of responsibility implementing this section within 180 days after November 28, 1990.

Section 136(j) specifically makes the following unlawful: refusal to prepare, maintain, or submit required records; knowing falsification of all or part of any application, information submitted to the Administrator, records required to be maintained, report filed, or any information marked and submitted as confidential; failure to file reports; and violation of any regulations promulgated pursuant to the statute. This enforcement provision is a potential barrier to electronic reporting and underlines the importance of ensuring that electronic records and reports can be verified in a judicial proceeding.

#### Section 136j Unlawful Acts

Potential barrier

(a)(2)(B) It shall be unlawful for any person to refuse to - (i) prepare, maintain, or submit any records required by (...); (ii) submit any reports required by (...); or (iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter; (...) (M) to *knowingly falsify all or part of any application for registration*, application for experimental use permit, *any information submitted* to the Administrator pursuant to section 136e of this title, *any records required to be maintained* pursuant to this subchapter, *any report filed* under this subchapter, or *any information marked as confidential* and submitted to the Administrator under any provision of this subchapter; (...) (N) who is a registrant, wholesaler, dealer, retailer, or other distributor to *fail to file reports* required by this subchapter; (...) (R) to *submit to the Administrator data known to be false* in support of a registration; or (S) to violate any regulation issued under section 136a(a) or 136q of this title.

## L. Imports and exports

Under section 1360, pesticides intended solely for export do not violate FIFRA when prepared or packed according to the foreign purchaser's specifications. If the pesticide is not registered for use in the United States and cannot be sold in the United States, the foreign purchaser must sign a statement acknowledging these facts. This provision could pose a potential barrier to electronic reporting unless EPA regulations are amended to authorize the foreign purchaser to use electronic reporting to sign the statement. In addition, a copy of the signed statement must be transmitted to the importing country's government. This has an ambiguous impact on electronic reporting, but EPA regulations could authorize electronic transmittal.

### Section 1360(a) Pesticides Intended for Export Only

Potential barrier/ Ambiguous

(...) no pesticide or device or active ingredient used in producing a pesticide intended solely for export (...) shall be deemed in violation of this subchapter - (1) when prepared or packed according to the specifications or directions of the foreign purchaser, (...) and (...) if, prior to export, the foreign purchaser has *signed a statement* acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.

A *copy of that statement* shall be transmitted to an appropriate official of the government of the importing country.

Section 1360 also requires the Secretary of the Treasury, in consultation with the EPA Administrator, to promulgate regulations for pesticides intended for export. The existing regulations (40 C.F.R. 168.75) do not specify whether electronic reporting may be used for the signed statement and copy, but this rulemaking authority could be used to authorize electronic transmissions of both the signed statement and the copy to the importing country's government.

## Section 1360 Regulation of Pesticides Intended for Export

No barrier

(e) The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) of this section.

## M. Pesticide storage, disposal, transportation, and recall

Section 136q(a) concerns the storage, disposal, and transportation of pesticides. Under this section, the Administrator may require the registrant or applicant for registration to submit data or information on safe storage and disposal methods for excess quantities of the pesticide as part of the registration requirements or in order to maintain an existing registration in effect. This section lists submission of labeling and provision of "evidence" as possible requirements, so it is unclear how electronic reporting would fulfill these requirements.

## Section 136q(a)(1) Data Requirements and Registration of Pesticides.

Ambiguous

The Administrator *may* require (...) that - (A) the registrant or applicant for registration of a pesticide *submit or cite data or information* regarding methods for the safe storage and disposal of excess quantities of the pesticide to support the registration or continued registration of a pesticide; (B) the *labeling* of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide, any container of the pesticide, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and (C) the registrant of a pesticide *provide evidence* of sufficient financial and other resources to carry out a recall plan under subsection (b) of this section, (...).

Section 136q(a)(2) authorizes the Administrator to issue rules containing requirements and procedures for those who store or transport pesticides and whose registrations have been suspended or canceled. This can be done by either regulation or as part of an order issued pursuant to section 136d. This provision does not pose any barrier to electronic reporting.

## Section 136q(a)(2) Storage and Transport of Suspended or Canceled Pesticides

No barrier

The Administrator *may by regulation*, or as part of an order issued under section 136d of this title or an amendment to such an order - (A) *issue requirements and procedures* to be followed by any person who stores or transports a pesticide the registration of which has been suspended or canceled; (B) issue requirements and procedures to be followed by any person who disposes of stocks of a pesticide the registration of which has been suspended; and (C) issue requirements and procedures for the disposal of any pesticide the registration of which has been canceled.

Section 136q(a)(3) grants similar rulemaking authority for containers, rinsates, and other materials relating to pesticides whose registration has been suspended or canceled. EPA regulations could incorporate some reporting requirements, and in turn provide for electronic reporting.

## Section 136q(a)(3) Containers, Rinsates, and Other Materials Relating to Suspended or Canceled Pesticides

No barrier

The Administrator *may by regulation* (...) (A) *issue requirements and procedures* to be followed by any person who stores or transports any container of a pesticide the registration of which has been suspended or canceled (...); (B) *issue requirements and procedures* to be followed by any person who disposes of stocks of any container, (...) rinsate, (...) or any other material used to contain or collect (...) the pesticide; and (C) *issue requirements and procedures* for the disposal of any container, (...) rinsate, (...) or any other material (...).

Section 136q(b) addresses the recall procedure for pesticides whose registration has been suspended or canceled. The Administrator is directed to order recall of a pesticide if its registration has been suspended or canceled and if recall is necessary to protect health or the environment. If voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as mandatory recall, the Administrator is directed to request the registrant to

submit a plan for the voluntary recall of the pesticide in question. Under section 136q(c)(1), a registrant may be eligible for reimbursement of storage costs incurred as a result of a voluntary recall if their recall plan meets criteria established by the Administrator by regulation. This provision does not pose a barrier to electronic reporting, and the EPA could by regulation authorize recall plans to be submitted electronically.

#### Section 136q(b)(2) Voluntary Recall of Pesticides

No barrier

If (...) the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to *submit* (...) *a plan* for the voluntary recall of the pesticide. (...)

If, on the other hand, the Administrator does not request the registrant to submit a recall plan, or a submitted plan is inadequate, section 136q(b)(3) requires the Administrator to issue regulations prescribing a mandatory recall plan.

## Section 136q(b)(3) Mandatory Recall of Pesticides

No barrier

If, after determining under paragraph (1) that a recall is necessary, the Administrator does not request the submission of a plan under paragraph (2) or finds such a plan to be inadequate, the Administrator **shall issue a regulation** that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor, or seller of the pesticide, or any successor in interest to such a person.

Section 136q(b)(4) lists requirements that the regulations authorized by section 136q(b)(4) might impose. The examples include taking reasonable steps to inform persons who may be holders of the pesticide of the terms of the recall regulation and of how those persons may tender the pesticide. This section may pose a barrier to electronic reporting unless EPA's regulations authorize electronic reporting for informing persons as a "reasonable step."

#### Section 136q(b)(4) Procedures for Mandatory Recall

**Ambiguous** 

A regulation issued under this subsection may require any person that is subject to the regulation to (...) (D) take such *reasonable steps as the regulation may prescribe to inform persons* who may be holders of the pesticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

## N. Authority of States

States are authorized by section 136v(a) to regulate the sale or use of any federally registered pesticide or device in the state. State regulations may not permit any sale or use prohibited by this subchapter, nor may they impose any labeling or packaging requirements that are different from those required under this subchapter. Section 136v(c) allows a state to provide registration

for additional uses within the state of federally registered pesticides in order to meet special local needs. Such additional uses must be in accord with the purposes of this subchapter and must not have been previously disapproved by the Administrator. States may promulgate regulations for pesticides within their jurisdiction, which could include authority for electronic reporting.

#### Section 136v Authority of States

No barrier

- (a) A State *may regulate* the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter. (...)
- (c)(1) A State *may provide registration* for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter (...).

## O. Rulemaking Authority of Administrator

Section 136w is a broad provisions authorizing the Administrator to promulgate regulations to carry out the provisions of FIFRA. Existing EPA regulations implementing FIFRA demonstrate that this general rulemaking authority could be used by EPA to authorize electronic reporting and information provision. For example, 40 C.F.R. section 157.20 consists of regulations promulgated pursuant to section 136w that address child-resistant packaging. Registrants are required to keep records of test data and other related information for as long as the registration is in effect. In addition, under 40 C.F.R. section 157.36, registrants are required to either submit the records or make them available to the Administrator for inspection and copying. So while the statutory language provides no barrier to electronic reporting, the existing regulations may have an ambiguous effect on an electronic reporting option. This general rulemaking authority can be used to amend those ambiguous regulations and to authorize electronic reporting.

#### Section 136w (a)(1) Regulations Implementing FIFRA's Provisions

No barrier

The Administrator is authorized, in accordance with the procedure described in paragraph (2), to *prescribe regulations* to carry out the provisions of this subchapter. (...)

Some registered pesticides are affected by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. et seq.). The regulations in 40 C.F.R. part 163 reflect this overlap in the provisions for certification of usefulness of pesticide chemicals for the purpose of setting a tolerance or securing an exemption. The statutory authority for this part is 21 U.S.C. 346a. The regulations may impact electronic reporting by, for example, requiring that requests for certification be submitted in writing along with a copy of the applicant's FIFRA registration or application for registration. 40 C.F.R. Section 163.4. Other regulations promulgated pursuant to section 136w's general rulemaking authority include the worker protection standards at 40 C.F.R. part 170 and certification of pesticide applicators regulations at 40 C.F.R. part 171.